



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

001,500 06/27/00

0 00 000

023672
SERIES: PATENT, LLP
700 THIRD AVE, 14TH FLOOR
NEW YORK, NY 10007

HM1000027

EXAMINER

NAME

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/578,587

Applicant(s)
Keri et al.

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/659,961.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

The preliminary amendments filed 4/19/00 and 4/16/01 are acknowledged. Claims 1 and 3-10 are being considered on the merits.

The numbering of claims is not accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). The present application contains original claims 1-8. Therefore, new, misnumbered, claims 14 and 15 have been renumbered 9 and 10 respectively. Claim 2 is cancelled. Claim 13 could not be cancelled in the absence of a claim having that number.

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not include the proof of Mary Balint as legal representative of deceased inventor Janos Balint. See MPEP 409.01(a).

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

The petition under 37 C.F.R. § 1.47(a) will be forwarded to Petitions Branch for consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for "*Aspergillus* bacterium strain". *Aspergillus* are fungi, not bacteria.

Claims 1 and 3-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of a "biomass" to be fermented. It is unclear what this term is intended to encompass. The terminology "fermentation liquor" is confusing. A better term would be "culture medium". Also what is intended by "dissolving mevinolin from the biomass" is unclear.

Claim 8 is confusing because of the use of multiple "or". Claims 5 and 7 are inconsistent in the recitation of a singular additive, yet encompasses all of the additives listed by using the term "and". It is recommended that proper Markush format be used, e.g. selected from the group consisting of A,B, AND C. See MPEP 2173.05(h)(a).

Claim 7 fails to find proper antecedent basis in claim 5 for triethylamine, which is C₆ and for diethylamine, which is C₅.

Claim 10 is vague and indefinite in the recitation of "*Aspergillus* bacterium strain". It is unclear what is intended.

Claims 1 and 3-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of mevinolin with *Aspergillus obscurus* MV-1 or *Aspergillus terreus*, does not reasonably provide enablement for its production with any

strain of *Aspergillus*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

From the record of the present written disclosure, strain *Aspergillus obscurus* MV-1 and *Aspergillus terreus* ATCC 20542 and an unidentified strain of *Aspergillus terreus* are the only strains of *Aspergillus* shown to be capable of the production of the required product. Therefore these are the only strains enabled by the present specification therefor, provided all deposit requirements are met..

It would require undue experimentation for one skilled in the art to determine which other strains of *Aspergillus* would be suitable for the claimed invention, in view of the recognized difficulty in isolating strains from nature, especially in the absence of a specific screening assay and because the present record fails to disclose the properties deemed to characterize members of the species *Aspergillus* as now claim designated. Ex parte Jackson, 217 U.S.P.Q. 804 (Bd. App. 1982).

The distinguishing properties of members of *Aspergillus obscurus* are not clear from the as-filed specification and are not readily apparent to one of ordinary skill in this art. The only strain contemplated by applicants and shown to be suitable for the production of mevinolin as claimed is strain *Aspergillus obscurus* MV-1 and strains of *Aspergillus terreus*. From the current record, it cannot be readily ascertained how or where other strains belonging to the species *Aspergillus* are obtainable to carry out the invention as claimed, and applicants have not provided any guidance in this regard.

The limited showing of just a few microorganisms with a particular activity is not sufficient to enable a claim drawn to any possible strain within the genus because the art of microbiology is unpredictable. One cannot assume that the ability of a few members of two species of particular microorganisms to perform a special process ensures that all other strains or mutants will have the same characteristics or capabilities. Further, the specification does not teach where the ordinary artisan find other strains belonging to the genus *Aspergillus* are obtainable to carry out the invention as claimed. Hence, the ordinary artisan would be forced to examine any

possible *Aspergillus* strain from any location. This would constitute undue experimentation.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

Claims 1 and 5-10 are rejected under 35 U.S.C. § 102(a) as being anticipated by Jekkel et al. (US patent 5,403,728). See, e.g. col. 7 et seq. wherein the treatment of biomass of *A. obscurus* MV-1 to obtain mevinolin is first with 2N NaOH, which would be expected to yield at a pH of about 7.5 to 10, and then with sulfuric acid at a pH of about 1.5.

Applicant cannot rely upon the foreign priority claimed to overcome this rejection, because even though the respective papers were filed in the parent case, a certified translation of said papers has not been made of record. See M.P.E.P. § 201.15.

Claims 1 and 3-10 are rejected under 35 U.S.C. § 103 as being unpatentable over Jekkel et al. U.S. Patent No. 5,403,728 taken with Nakamura et al.

Jekkel et al. as applied *supra* differs from the claimed invention in that the reference does not teach the precise pH values and additives recited.

However, Nakamura et al. teach the recovery of derivative of mevinolin from the respective biomass by adjusting the pH first to 10 and then to 3, which is within the range of the claimed process (See, e.g., page 1597). The reference also teaches the addition of ethyl acetate in the recovery process page 1597, last line. The reference differs from the claimed invention in that the product recovered is not mevinolin, but rather 3 α -Hydroxy-3,5-dihydromonacolin L, a product closely structurally related to mevinolin.

Although the references do not teach the precise pH values and additives recited, the adjustment of process parameters such as pH and the addition of a variety of solvents to a process

of recovery of antibiotics for optimization purposes is deemed to be well within the ordinary skill of the art.

Consequently, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Jekkel et al. by modifying the pH and additives, as suggested by the teachings of Nakamura et al. for a process for the recovery of mevinolin in addition or instead of 3 α -Hydroxy-3,5-dihydromonacolin L with a reasonable expectation of success, for the expected benefit of improving the yield and purity of mevinolin as a cholesterol-lowering drug.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant cannot rely upon the foreign priority claimed to overcome this rejection, because even though the respective papers were filed in the parent case, a certified translation of said papers has not been made of record. See M.P.E.P. § 201.15.

Claims 1 and 3-10 are rejected under 35 U.S.C. § 103 as being unpatentable over Nakamura et al. taken with Tsujita et al. and Endo et al.

Nakamura et al. teach the recovery of a derivative of mevinolin from the cultured biomass by adjusting the pH first to 10 and then to 3, which is within the range of the claimed process (See, e.g., page 1597). The reference also teaches the addition of ethyl acetate in the recovery process (See, e.g., page 1597, last line). The reference differs from the claimed invention in that the product recovered is not mevinolin, but rather 3 α -Hydroxy-3,5-dihydromonacolin L, a product closely structurally related to mevinolin. However, Tsujita et al. teaches the recovery of mevinolin from biomass filtrate using a pH of about 10, while Endo et al. teach a pH of about 3 for the same process.

Although the references do not teach the precise pH values and additives recited, the adjustment of process parameters such as pH and the addition of a variety of solvents to a process of recovery of antibiotics for optimization purposes is deemed to be well within the ordinary skill of the art.

Consequently, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Nakamura et al. by using the process for the recovery of mevinolin in addition or instead of 3 α -Hydroxy-3,5-dihydromonacolin L with a reasonable expectation of success, in view of the teachings of Tsujita et al. and Endo et al. for the expected benefit of improving the yield and purity of mevinolin as a cholesterol-lowering drug.

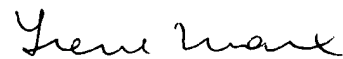
Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .



Irene Marx
Primary Examiner
Art Unit 1651